

CLAIMS

We claim:

1. A method for predicting the risk of a disease, comprising the steps of:
 - a) providing a saliva sample from a subject;
 - b) isolating a mucin in said saliva sample to produce an isolated mucin; and
 - c) quantitating the content of a component of said isolated mucin to predict the risk of a disease in said subject.
2. The method of Claim 1, wherein said saliva sample is a stimulated saliva sample.
3. The method of Claim 1, wherein said saliva sample is an unstimulated saliva sample.
4. The method of Claim 1, wherein said component is total apomucin.
5. The method of Claim 1, wherein said component is total carbohydrate.
6. The method of Claim 1, wherein said component is sialic acid.
7. The method of Claim 1, wherein said mucin is MUC7 mucin.
8. The method of Claim 1, wherein said mucin is MUC5AC mucin.
9. The method of Claim 1, wherein said mucin is MUC5B mucin.
10. The method of Claim 1, further comprising the step of reporting the content of said component in said isolated mucin as units per milliliter of said saliva sample.
11. The method of Claim 1, further comprising the step of assessing the risk of said disease as high, medium or low.
12. The method of Claim 1, further comprising the step of assessing the risk of future development of said disease in said subject.

1 **13.** The method of Claim 12, further comprising the step of assessing the risk
2 of future development of said disease in said subject at subsequent ages.

1 **14.** The method of Claim 1, wherein said isolating step comprises isolating
2 said mucin using SDS-PAGE.

1 **15.** The method of Claim 1, wherein said quantitating step comprises
2 specifically binding said component in said isolated mucin.

1 **16.** The method of Claim 15, wherein said binding comprises direct binding or
2 facilitated binding.

1 **17.** The method of Claim 16, wherein said direct binding comprises dye-
2 binding.

1 **18.** The method of Claim 16, wherein said facilitated binding comprises
2 linking a specifically binding member pair to a surface that specifically binds to
3 said component of said isolated mucin.

1 **19.** The method of Claim 18, wherein said specifically binding member pair is
2 selected from the group consisting of antibodies and lectins.

1 **20.** The method of Claim 1, wherein said subject is a human.

1 **21.** The method of Claim 20, wherein said human is selected from the group
2 consisting of males and females.

1 **22.** The method of Claim 20, wherein said subject is aged between 18 and 35
2 years old.

1 **23.** The method of Claim 1, wherein said disease is selected from the group
2 consisting of dental caries, periodontal diseases, pulmonary diseases, respiratory
3 diseases, cardiovascular diseases, diabetes, perinatal disorders, mucosal
4 infections, oral cancers, pharyngeal cancers, precancerous lesions, associated
5 autoimmune disorders, HIV, osteoporosis, and a combination thereof.

1 **24.** The method of Claim 23, wherein said periodontal diseases are selected
2 from the group consisting of gingivitis, adult periodontitis, early-onset
3 periodontitis, and a combination thereof.

1 **25.** The method of Claim 23, wherein said cardiovascular diseases are selected
2 from the group consisting of heart attack, stroke and atherosclerosis.

1 **26.** The method of Claim 23, wherein said perinatal disorders are selected
2 from the group consisting of low birth weight and preterm births.

1 **27.** The method of Claim 23, wherein said diabetes is Type 1 diabetes or Type
2 2 diabetes.

1 **28.** The method of Claim 23, wherein said mucosal infections are selected
2 from the group consisting of oral candidiasis, herpes simplex virus infections,
3 herpes zoster virus infections, varicella zoster virus infections, human
4 papillomavirus infections, oral human papillomavirus infections, recurrent
5 aphtous ulcers, and combinations thereof.

1 **29.** The method of Claim 28, wherein said herpes simplex virus is Type 1 or
2 Type 2.

1 **30.** The method of Claim 23, wherein said disease is dental caries.

1 **31.** The method of Claim 30, wherein said dental caries is selected from the
2 group consisting of early-onset dental caries, adult dental caries, root caries, DFT,
3 DMF, and DMFS.

1 **32.** A method for reducing the risk of a disease, comprising the steps of:
2 a) providing a saliva sample from a subject;
3 b) isolating a mucin in said saliva sample to produce an isolated
4 mucin;
5 c) quantitating the content of a component in said isolated mucin; and
6 d) administering a therapeutic reagent to said subject when the

7 content of said component in said isolated mucin significantly falls below the
8 level expressed in an oral fluid standard.

1 33. The method of Claim 32, wherein said saliva sample is a stimulated saliva
2 sample.

1 34. The method of Claim 32, wherein said saliva sample is an unstimulated
2 saliva sample.

1 35. The method of Claim 32, wherein said component is total apomucin.

1 36. The method of Claim 32, wherein said component is total carbohydrate.

1 37. The method of Claim 32, wherein said component is sialic acid.

38. The method of Claim 32, wherein said mucin is MUC7 mucin.

39. The method of Claim 32, wherein said mucin is MUC5AC mucin.

40. The method of Claim 32, wherein said mucin is MUC5B mucin.

41. The method of Claim 32, wherein said isolating step comprises isolating
said mucin using SDS-PAGE.

42. The method of Claim 32, wherein said quantitating step comprises
specifically binding said component of said isolated mucin.

1 43. The method of Claim 42, wherein said binding comprises direct binding or
2 facilitated binding.

1 44. The method of Claim 43, wherein said direct binding comprises dye-
2 binding.

1 45. The method of Claim 43, wherein said facilitated binding comprises
2 linking a specifically binding member pair to a surface that specifically binds to
3 said component of said isolated mucin.

1 **46.** The method of Claim 45, wherein said specifically binding member pair is
2 selected from the group consisting of antibodies and lectins.

1 **47.** The method of Claim 32, wherein said subject is a human.

1 **48.** The method of Claim 47, wherein said human is selected from the group
2 consisting of males and females.

1 **49.** The method of Claim 32, wherein said subject is aged from between 18 to
2 35 years of age.

1 **50.** The method of Claim 32, wherein said disease is selected from the group
2 consisting of periodontal diseases, pulmonary diseases, respiratory diseases,
3 cardiovascular diseases, diabetes, perinatal disorders, mucosal infections, oral
4 cancers, pharyngeal cancers, precancerous lesions, associated autoimmune
5 disorders, HIV, osteoporosis, and a combination thereof.

1 **51.** The method of Claim 50, wherein said periodontal diseases are selected
2 from the group consisting of gingivitis, adult periodontitis, early-onset
3 periodontitis, and a combination thereof.

1 **52.** The method of Claim 50, wherein said cardiovascular diseases are selected
2 from the group consisting of heart attack, stroke and atherosclerosis.

1 **53.** The method of Claim 50, wherein said perinatal disorders are selected
2 from the group consisting of low birth weight and preterm births.

1 **54.** The method of Claim 50, wherein said diabetes is Type 1 diabetes or Type
2 2 diabetes.

1 **55.** The method of Claim 50, wherein said mucosal infections are selected
2 from the group consisting of oral candidiasis, herpes simplex virus infections,
3 herpes zoster virus infections, varicella zoster virus infections, human
4 papillomavirus infections, oral human papillomavirus infections, recurrent
5 aphtous ulcers, and combinations thereof.

1 **56.** The method of Claim 55, wherein said herpes simplex virus is Type 1 or
2 Type 2.

1 **57.** The method of Claim 32, wherein said disease is dental caries.

1 **58.** The method of Claim 57, wherein said dental caries is selected from the
2 group consisting of early-onset dental caries, adult dental caries, root caries, DFT,
3 DMF, and DMFS.

1 **59.** The method of Claim 57, wherein said therapeutic reagent is an anti-caries
2 reagent.

1 **60.** The method of Claim 32, wherein said oral fluid standard comprises a
2 sample from a normal control.

1 **61.** A diagnostic kit for detecting a disease comprising:

- 2 a) a means for collecting a saliva sample;
3 b) a means for isolating a mucin in said saliva sample, to produce an
4 isolated mucin;
5 c) a means for measuring the amount of a component in said isolated
6 mucin; and
7 d) an oral fluid standard for comparing the amount of said component
8 in said isolated mucin.

1 **62.** The method of Claim 61, wherein said oral fluid standard comprises the
2 content of said component in said mucin of a normal subject.

1 **63.** The diagnostic kit of Claim 61, wherein said disease is selected from the
2 group consisting of dental caries, periodontal diseases, pulmonary diseases,
3 respiratory diseases, cardiovascular diseases, diabetes, perinatal disorders,
4 mucosal infections, oral cancers, pharyngeal cancers, precancerous lesions,
5 associated autoimmune disorders, HIV, osteoporosis, and a combination thereof.

64. The diagnostic kit of Claim 63, wherein said periodontal diseases are selected from the group consisting of gingivitis, adult periodontitis, early-onset periodontitis, and a combination thereof.

65. The diagnostic kit of Claim 63, wherein said cardiovascular diseases are selected from the group consisting of heart attack, stroke and atherosclerosis.

66. The diagnostic kit of Claim 63, wherein said perinatal disorders are selected from the group consisting of low birth weight and preterm births.

67. The diagnostic kit of Claim 63, wherein said diabetes is Type 1 diabetes or Type 2 diabetes.

68. The diagnostic kit of Claim 63, wherein said mucosal infections are selected from the group consisting of oral candidiasis, herpes simplex virus infections, herpes zoster virus infections, varicella zoster virus infections, human papillomavirus infections, oral human papillomavirus infections, recurrent aphthous ulcers, and combinations thereof.

69. The diagnostic kit of Claim 68, wherein said herpes simplex virus is Type 1 or Type 2.

70. The diagnostic kit of Claim 63, wherein said disease is dental caries.

71. The diagnostic kit of Claim 69, wherein said dental caries is selected from the group consisting of early-onset dental caries, adult dental caries, root caries, DFT, DMF, and DMFS.